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APPLICATION NO.	F	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,243	36,243 12/16/2003		Jingrong Cui	034536-0905	4672
22428	7590	06/16/2004		EXAMINER	
FOLEY A	ND LAR	DNER	PATEL, SUDHAKER B		
SUITE 500 3000 K STREET NW				ART UNIT	PAPER NUMBER
5550 11 5 11	WASHINGTON, DC 20007			1624	
				DATE MAILED: 06/16/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
	10/736,243	CUI ET AL.					
Office Action Summary	Examiner	Art Unit					
·	Sudhaker B. Patel, D.Sc.Tech.	1624					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1) Responsive to communication(s) filed on 16 De	)⊠ Responsive to communication(s) filed on <u>16 December 2003</u> .						
2a) ☐ This action is <b>FINAL</b> . 2b) ☐ This	action is non-final.						
3) Since this application is in condition for allowan	·						
closed in accordance with the practice under E.	x parte Quayle, 1935 C.D. 11, 45	3 O.G. 213.					
Disposition of Claims							
4) Claim(s) 1-20 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) 1-20 are subject to restriction and/or election requirement.							
Application Papers							
9) The specification is objected to by the Examiner	•						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. § 119							
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
Attachment(s)	-						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary ( Paper No(s)/Mail Da 5) Notice of Informal Pa						

Art Unit: 1624

## **DETAILED ACTION**

This is a jumbo application, and is a DIV of the U.S. Application Sr. NO. 10023488 filed 12/20/2001, now U.S.P. 6677368, which consists of columns 1-594.

Claims 1,2,3, 5,10,18,20 involve multiple of compounds, their simple compositions, their binary complex compositions, and various method of uses related to pharmacological properties, receptor tyrosine kinase, cellular tyrosine kinase, or serine-threonine kinase biological activities which different in nature, and various method for treating disorders in a human. Examiner has reviewed the instant application consisting of compound claims 1-3,20, simple composition claims 16,17, complex composition claims 18,19, method claims 4-8 dependent on the pharmacological properties, and method for treating disorders in human claims 9-15, and found that this application is not ready for allowance in as is condition for the reasons stated bellow.

## Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims (in part) 1,4,6,9,12,13,15,16,17, drawn to compounds, simple compositions, and a single method of treatment for compounds of generic Formula (I), wherein R1 is aryl, R3/R4 or R4/R5 not forming a fusion with 5-membered pyrrole ring, classified in class 548, subclasses various depending on the nature of the variables R1-R5. If this group is elected further restriction will be requires as there are many unknowns.

    Additionally, a single, specific species from the working examples must be disclosed with all variables exactly and definitely defined.

Art Unit: 1624

## Applicants had elected this invention for the parent U.S. Application Sr. No. 10023488, filed 12/20/2001, now U.S.P. 6677368.

- II. Claims (in part) 1,4,6,9,12,13,15,16,17, drawn to compounds, simple compositions, and a single method of treatment for compounds of generic Formula (I), wherein R1 is heteroaryl, classified various classes, subclasses various, in addition to class 548, depending on the nature of variable R1.e.g. when R1 is pyridine, quinoline, isoquinoline the class will be 546; when R1 is pyrimidine the class will be 544, subclass 242; when R1 is purine, although the main class is 544, subclass will be 264; when R1 is furan, thien the class will be 549. If this group is elected further restriction will be requires as there are many unknowns. Additionally, a single, specific species from the working examples must be disclosed with all variables exactly and definitely defined.
- III. Claims (in part) 2, 4,6,9,12,13,15,16,17, drawn to compounds, simple compositions, and a single method of treatment for compounds of generic Formula (I), wherein R3/R4 or R4/R5 form a bicyclic fusion with the pyrrole ring wherein the second ring of the bicyclic fusion is <a href="https://example.com/heterocycle">heterocycle</a> (= pyranone, pyridone), classified in classes 5438, 549, 546, subclasses various depending on the nature of R1, R1, R6 variables. If this group is selected further restriction will be required as there are many unknowns.

Art Unit: 1624

Additionally, a single, specific species from the working examples must be disclosed with all variables exactly and definitely defined.

- IV. Claims (in part) 3,4,6,9,16,17 drawn to compounds, simple compositions, and a single method of treatment for compounds of generic Formula (I), wherein R3/R4 or R4/R5 form a bicyclic fusion with the pyrrole ring wherein the second ring of the bicyclic fusion is non-heterocycle (=saturated cyclopentane, cyclohexane), classified in class 548, subclass 469,470.
- V. Claims (in part) 5,7,8,9,10,11,14,15,18,19,20, drawn to compounds, compositions, and method of use other than above stated inventions of groups I-IV, classified in class 548, class 514, subclasses various depending on the nature of variables R1, R2, R8, R10, R11, R6/R7.

The inventions are distinct, each from the other because of the following reasons:

The compounds of Groups I-V are drawn to:

- (1). Structurally diverse compounds that are made and used independently of each other;
- (2). Compounds are separately classified;
- (3) Classes will require separate literature searches;
- (4) Compounds are not art recognized equivalents, and additionally,
- (5). The groups lack unity of invention(see MPEP 803.02).

Based on above stated data i.e. (1) - (5)., claim 1 also lacks unity of invention.

2. Inventions I-V are different groups consisting of product, compositions of products and process of their uses. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed

Art Unit: 1624

can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, compounds of U.S.P. 5792783 & WO35909 can also be used for the utility as claimed herein.

- 3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-V, restriction for examination purposes as indicated is proper.
- 4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
- 5. Claims 1,2,3,4,59,10,16,19,20 are generic to a plurality of disclosed patentably distinct species comprising: (1). R1 component is presented as aryl or heteroaryl, which can be optionally, substituted aryl or heteroaryl, which can be further substituted by one or more of R2 component, which can be aryl or heterocycle. (2). R3/R4 or R4/R5 can be forming a fusion or can be open ended, and consisting of variables R6, R7, R2, R10, R8, R10, R11. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from the working examples, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Art Unit: 1624

6. A telephone call was made to ATTY. Ms. B. Burrous on 6/7/04 to request an oral election to the above restriction requirement, but did not result in an election being made. See attached interview summary.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker B. Patel, D.Sc.Tech. whose telephone number is (571) 272-0671. The examiner can normally be reached on 6:30 to 5:00 pm (Monday-Thursday). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund J. Shah can be reached on (571) 272 0674 or Sr. Examiner Mr. Richard Raymond at (571) 272 0673 or Mr. James O. Wilson at (571) 272-0661. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308 4556 for regular communications and 703 308 4556 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235. Information regarding the status of an application

Art Unit: 1624

may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sudhaker B. Patel, D.Sc. Tech.

June 14, 2004

MUKUN SHAPE

SUPERVISORY PATENT

**EXAMINER** 

ART UNIT 1624/1623